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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,804	04/17/2001	Gebre-mariam Mesfin	6267.N	6782

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EXAMINER
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JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/836,804

**Applicant(s)**

MESFIN ET AL.

**Examiner**

Shaojia A Jiang

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2003 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed December 1, 2003, and amendment and response to the Final Office Action (mailed June 18, 2003), filed December 1, 2003 wherein claims 1-6 have been amended.

Currently, claims 1-12 are pending in this application.

Claims 1-12 are examined on the merits herein.

Applicant's remarks filed on December 1, 2003 with respect to the rejection of claim 1-6 made under 35 U.S.C. 103(a) as being unpatentable over Batts et al. (WO 9925344) for reasons of record stated in the Office Action dated June 18, 2003, have been considered and are found persuasive to remove this particular rejection since the compounds in the cited WO patent are deemed not read on the instant compounds of formula I because sulfur atom is not contained in the compounds of WO 9925344. Therefore, the said rejection is withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6 and 12 have been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for the negative limitation, "said mammal is not suffering from a bacterial infection". The original specification discloses a vertebrate mammal suffering bone diseases broadly.

Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hester et al. (WO 9854161) in view of Nair et al. for the same reasons of record stated in the Office Action dated June 18, 2003.

Hester et al. discloses that the instant active compounds as being antibacterial agents are useful in pharmaceutical compositions and methods for treating or combating bacterial infections in animals. Hester et al. also discloses that the instant active compounds are administered in the instant range orally and/or parentally. Hester et al. further discloses methods of manufacture of the instant compounds. See abstract, page 1-28, page 32 line 27 to page 33 line 13, page 42-81, page 109 lines 24-27 and claim 3 therein.

Hester et al. does not expressly disclose the employment of the instant active compounds in a method of treating osteoporosis in a vertebrate mammal.

Nair et al. teach that bacteria is an important cause of bone diseases and induce bone destruction and bone diseases such as osteoporosis, and many bacteria are capable of stimulating bone matrix loss and bone diseases such as osteoporosis. See

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title and Introduction and page 2371. Nair et al. also teach that the mechanism of bacterially induced bone destruction including osteoporosis (see the entire article).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant active compounds in a method of treating osteoporosis in a vertebrate mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant active compounds in a method of treating osteoporosis in a vertebrate mammal because active compounds herein are known antibacterial agents and known to be useful broadly in methods for treating or combating bacterial infections in animals according to Hester et al. Bacteria are known to be important cause of bone diseases, to induce bone destruction which would result in osteoporosis, and to stimulate bone matrix loss according to Nair et al. Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds known as antibacterial agents would have beneficially therapeutic effect on the treatment osteoporosis in a vertebrate mammal.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (WO 9912914) in view of Nair et al. of record stated in the Office Action dated June 18, 2003.

Yoshida et al. discloses that active compounds therein within the instant claim as antibacterial agents exhibit excellent antibacterial activity. Yoshida et al. further discloses methods of manufacture of the instant compounds. See abstract.

Yoshida et al. do not expressly disclose the employment of the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal. Yoshida et al. do not also discloses that the instant active compounds are administered in the instant range orally and/or parentally.

Nair et al. teach that bacteria is an important cause of bone diseases and induce bone destruction and bone diseases such as osteoporosis, and many bacteria are capable of stimulating bone matrix loss and bone diseases such as osteoporosis. See title and Introduction and page 2371. Nair et al. also teach that the mechanism of bacterially induced bone destruction including osteoporosis (see the entire article).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant active compounds in a method of treating osteoporosis in a vertebrate mammal, and to administer the active compounds herein in the instant range orally and/or parentally.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant active compounds in a method of treating osteoporosis in a vertebrate mammal because active compounds herein are known antibacterial agents and known to exhibit excellent antibacterial activity in animals according to Yoshida et al. Bacteria are known to be important cause of bone diseases, to induce bone destruction, and to stimulate bone matrix loss according to Nair et al.

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Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds known as antibacterial agents would have beneficially therapeutical effect on the treatment or prevention of osteoporosis, bone resorption, or other bone disease in a vertebrate mammal. Additionally, one of ordinary skill in the art would have been motivated to administer the active compounds herein in the instant range orally and/or parentally since the optimization of amounts of active agents to be administered and determination of routes of administration from those well known in the art is considered well within the skill of artisan, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Applicant's remarks filed on December 1, 2003 with respect to the above two rejections made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as discussed above.

Again, Applicant argument that treating bone destroying infection would not be obvious to treat osteoporosis, is not found convincing. As discussed above and in the previous Office Action, bone destroying infection or septic arthristis (bacterial infection) is known to tightly associated with bone diseases, osteoporosis and bone resorption, to induce bone destruction, and to stimulate bone matrix loss.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.



As discussed in previous Office Actions, Applicant's results on "Use of Compounds" of the specification at pages 44-45 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. The example herein merely demonstrate the employment of one particular compound within the instant claims in the treatment for increasing bone mass and density, but not particularly treating osteoporosis. Thus, the evidence in the example is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active compounds in the claimed methods of treating various bone diseases herein. See MPEP § 716.02(d). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

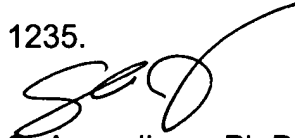
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The

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fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

A handwritten signature in black ink, appearing to read 'S. Anna Jiang', with a stylized, flowing script.

S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
February 5, 2004